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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/775,750	02/02/2001	Berend Jongsma	AHP-98248 P1	9381

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EXAMINER	
FOLEY, SHANON A	
ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 11/04/2002 15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/775,750	JONGSMA ET AL.	
	Examin r	Art Unit	
	Shanon Foley	1648	

-- Th MAILING DATE of this communication appears on the cov r sheet with the correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 August 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15,16,18,19,21,22 and 24-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15,16,18,19,21,22 and 24-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

In paper no. 14, applicant cancelled claims 1-14, 23, amended claims 15, 16, 24, and added new claims 25-29. Claims 15, 16, 18, 19, 21, 22, and 24-29 are under consideration.

Double Patenting

Claim 28 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 29. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Claim 28 depends on claim 24 and requires that the vaccine contains $10^{0.0}$ EID_{50} per dose to about $10^{2.0}$ EID_{50} per dose. Claim 29 depends from claim 28 and recites the identical limitation. These claims are substabtial duplicates of one another and applicant is required to cancel one to obviate this objection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 15, 16, 18, and 24-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 15, 24, and 25 recite "consists essentially of" rather than "comprising". It is unclear which elements are excluded from the vaccine claims or which steps are intended to be omitted from the method claims by the new claim language. There is no clear definition provided in the specification for ingredients are steps that would materially affect the method and

vaccine claims. Therefore, the "consisting essentially of" language in the claims is being interpreted as "comprising". See the MPEP § 2111.03. This rejection also affects dependent claims 16, 18, and 26-29.

It is noted that a previous rejection against claim 13 was set forth in the last Office action for the same grounds. The rejection is now moot because applicant cancelled claim 13. However, the issue still remains and applicant offered no explanation to remedy the substantive issue.

Claim 18 remains rejected for reasons of record. Applicant traverses this rejection on the grounds that it is now accepted practice to utilize terms that discourage potential infringers from circumventing the claims by using *de minimis* amounts. These arguments have been fully considered, but are found unpersuasive because there are no guidelines taught in the instant disclosure that would indicate what would be considered a substantial amount. Therefore, the term remains indefinite, see the MPEP section 2173.05 (b).

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 15, 16, 18, 24-29 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 15, 24, and 25 recite, " consisting essentially of" for the composition and method claims. There is no support in the specification for excluding ingredients or steps that are

encompassed by the original claim language, "comprising". Applicant has not pointed to support for this new claim language in the original specification and the examiner is unable to find support for this language or concept in the disclosure. This rejection also affects claims 16, 18, and 26-29.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 15, 16, 18, 19, 21, 22, and 24-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wakenell et al. for reasons of record.

Applicant argues that Wakenell et al. does not teach a commercially available vaccine that has not been approved for commercial use that is reconstituted and ready for *in ovo* administration. Applicant also argues that the reference teaches away from the instant invention and quotes a passage that essentially states that the diluted form of the vaccine did not improve hatchability.

Applicant's arguments and review of the reference have been fully considered, but are found unpersuasive. It is conceded that Wakenell et al. teaches mere dilution of the commercially available vaccine did not improve hatchability from the passage recited by applicant, which is found in the paragraph bridging pages 934-935. It is also noted that the claims require that the infectious bronchitis virus (IBV) is a live, avirulent strain (emphasis added). Wakenell et al. teaches that the undiluted and diluted vaccines are virulent, see "V-IBV"

in table 1 on page 935 and the paragraph bridging pages 933-934. Wakenell et al. teaches that the commercially available virulent strain became avirulent after tissue culture passage, see the abstract, results, and discussion section. For vaccination, each egg was inoculated with 0.1 mL of the desired virus dilution (virulent and avirulent passaged strains), see the first full paragraph on page 934. Therefore, Wakenell et al. teaches a vaccine comprising a live, avirulent IB virus that is commercially available and not approved for embryo administration, reconstituting the virus after serial passage to render the virus avirulent and a method of *in ovo* vaccination using this virus. Wakenell et al. also teaches that that the percentage of hatchability between 75 and 90% with the passaged vaccine, see Table 1 on page 935.

Applicant argues that the teaching of Sharma et al. do not remedy the shortcoming of Wakenell et al. because the reference does not discuss commercial vaccines that are reconstituted for in ovo vaccine purposes.

Applicant's arguments have been fully considered and are found persuasive. It is determined that the teachings of Sharma et al. are irrelevant in view of the teachings of Wakenell et al. discussed above.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon Foley whose telephone number is (703) 308-3983. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (703) 308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4426 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Shanon Foley
November 6, 2002

JAMES HOUSEL 11/4/02
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600